

Formula I

wherein, as valence permits,

R₂, R₃, R₄, and R₅ independently for each occurrence, represent one or more substituents

selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R₆, R₇, and R'₇ are absent or represent, independently for each occurrence, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$, or

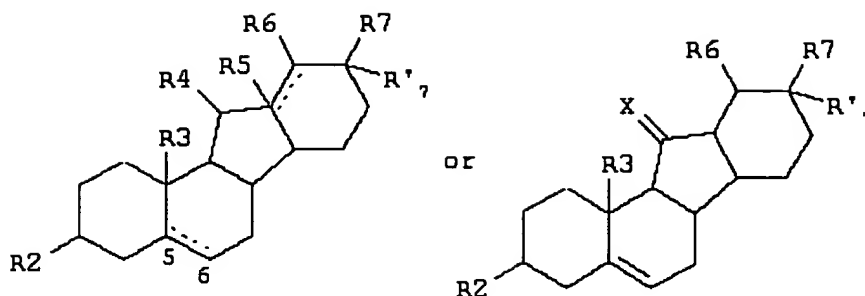
R₆ and R₇, or R₇ and R'₇, taken together form a ring or polycyclic ring;

with the proviso that at least one of R₆, R₇, or R'₇ is present and includes a primary or secondary amine;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

m is an integer in the range 0 to 8 inclusive.

5. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to a patient a composition comprising a purified steroidal alkaloid represented in the general formula (II), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula II

wherein

R_2 and R_4 , independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_3 , and R_{5a} , independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_6 , R_7 , and $R'7$ are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$, or

R_6 and R_7 , or R_7 and $R'7$, taken together form a ring or polycyclic ring,

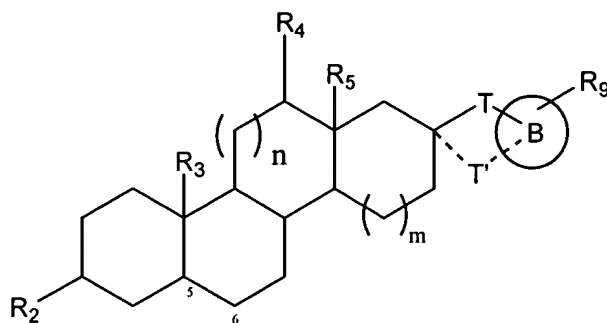
with the proviso that at least one of R_6 , R_7 , or $R'7$ is present and includes a primary or secondary amine;

R_8 represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

m is an integer in the range 0 to 8 inclusive; and

X represents O or S.

6. (Amended Twice) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified alkaloid represented in the general formula (III), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula III

wherein

R₂ and R₄ independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₃ and R₅ independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

B represents monocyclic or polycyclic groups;

T represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-10 bond lengths;

T' is absent, or represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-3 bond lengths, wherein if T and T' are present together, then T and T' taken together with the ring B form a covalently closed ring of 5-8 ring atoms;

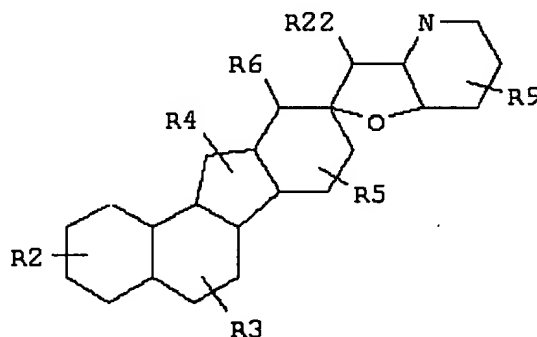
3
cont.

R₉ represent one or more substitutions to the ring B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$; and

n and m are, independently, zero, 1 or 2;

with the proviso that T, T', B and R₉, taken together include at least one primary or secondary amine.

7. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (IV), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula IV

wherein

R₂, R₃, R₄, and R₅ independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

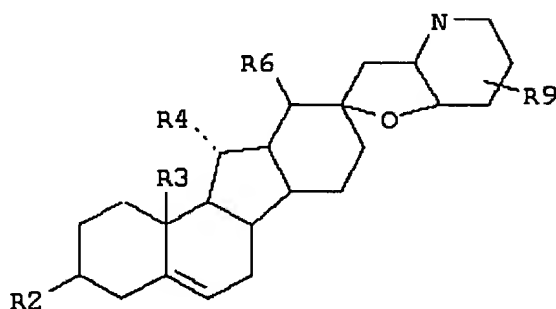
R_6 is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_8 represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

R_9 represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$; and

R_{22} is absent or represents an alkyl, an alkoxyl or -OH.

8. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (V) or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula V

wherein

R_2 and R_4 independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines,

carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_3 independently for each occurrence, represents one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_6 is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, $=O$, $=S$, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_8 represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

R_9 represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, $=O$, $=S$, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$.

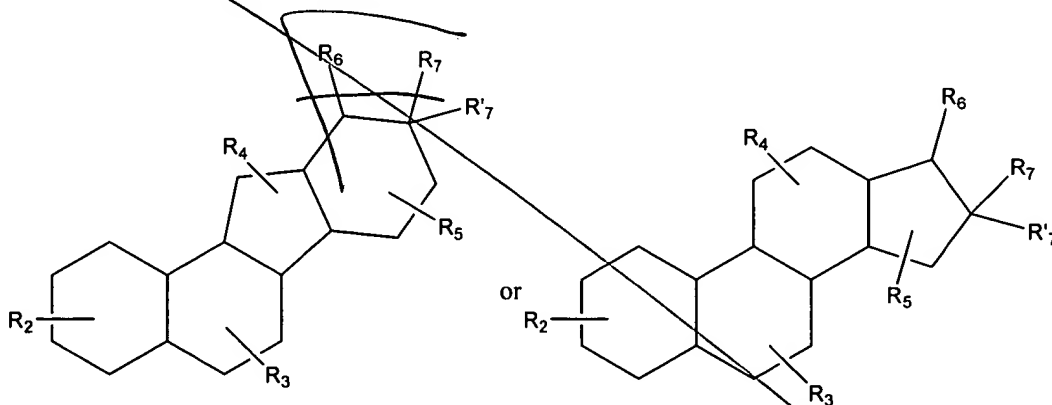
11. (Amended) The method of any of claims 3-8, wherein the steroidal alkaloid does not substantially interfere with the biological activity of such steroids as aldosterone, androstane, androstene, androstenedione, androsterone, cholecalciferol, cholestane, cholic acid, corticosterone, cortisol, cortisol acetate, cortisone, cortisone acetate, deoxycorticosterone, digitoxigenin, ergocalciferol, ergosterol, estradiol-17- α , estradiol-17- β , estriol, estrane, estrone, hydrocortisone, lanosterol, lithocholic acid, mestranol, β -methasone, prednisone, pregnane, pregnenolone, progesterone, spironolactone, testosterone, or triamcinolone.

12. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind a nuclear hormone receptor.

13. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind estrogen or testosterone receptors.

14. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid has no estrogenic activity at therapeutic concentrations.
15. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 mM or less.
16. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 μ M or less.
17. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 nM or less.
20. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is administered as part of a therapeutic or cosmetic application.
22. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is applied as a topical formulation.

24. (Amended) A pharmaceutical preparation formulated for topical application comprising steroidal alkaloid is represented in the general formula (I), or unsaturated forms thereof and/or seco-, nor- or homo- derivatives thereof:



Formula I

wherein, as valence and stability permit,

R₂, R₃, R₄, and R₅ independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

ε₆
cont.
R₆, R₇, and R'₇ are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈, or

R₆ and R₇, or R₇ and R'₇, taken together form a ring or polycyclic ring, substituted or unsubstituted, with the proviso that at least one of R₆, R₇, or R'₇ is present and includes a primary or secondary amine;

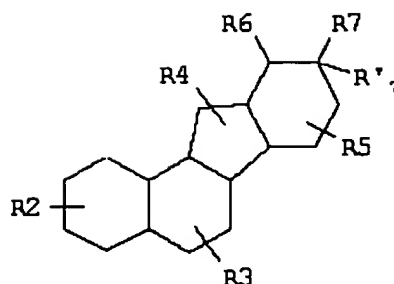
R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

m is an integer in the range 0 to 8 inclusive.

ε₇
26. (Amended) A process for manufacturing a medicament comprising formulating a steroid alkaloid inhibitor of a hedgehog signal transduction pathway in a pharmaceutically acceptable excipient to form a sterile medicament for treating unwanted hair growth or inhibiting spermatogenesis.

The claims presented above incorporate changes as indicated by the marked-up versions below.

3. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to a patient a composition comprising a purified steroidal alkaloid represented in the general formulas (I), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula I

wherein, as valence permits,

R_2 , R_3 , R_4 , and R_5 ; independently for each occurrence, represent one or more substituents ~~substitutions to the ring to which each is attached, for each occurrence, independently~~ ~~represent~~ selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or - $(CH_2)_m-R_8$;

R_6 , R_7 , and R'_7 ; are absent or represent, independently for each occurrence, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$, or

R_6 and R_7 , or R_7 and R'_7 , taken together form a ring or polycyclic ring;

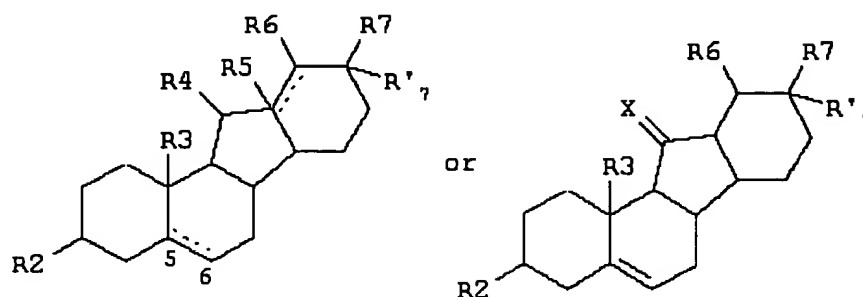
with the proviso that at least one of R_6 , R_7 , or R'_7 is present and includes a primary or secondary amine;

R_8 represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

m is an integer in the range 0 to 8 inclusive.

5. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to a patient a composition comprising a purified steroidal alkaloid

represented in the general formula (II), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula II

wherein

R₂, and R₃, R₄, and R₅, represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₃, and R₅, independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₆, R₇, and R'₇, are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈, or

R₆ and R₇, or R₇ and R'₇, taken together form a ring or polycyclic ring,

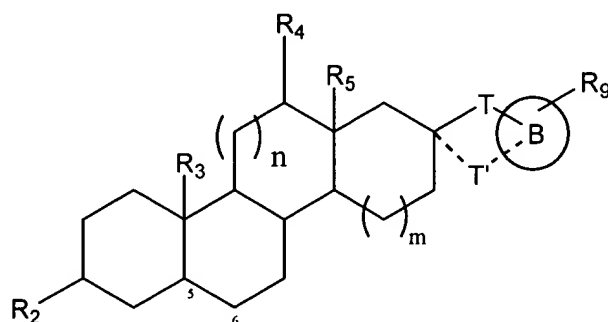
with the proviso that at least one of R₆, R₇, or R'₇ is present and includes a primary or secondary amine;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

m is an integer in the range 0 to 8 inclusive; and

X represents O or S.

6. (Amended Twice) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified alkaloid represented in the general formula (III), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula III

wherein

~~R₂, and R₃, R₄, and R₅, represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent independently for each occurrence,~~
represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₃, and R₅, independently for each occurrence, represent one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

B represents monocyclic or polycyclic groups;

T represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-10 bond lengths;

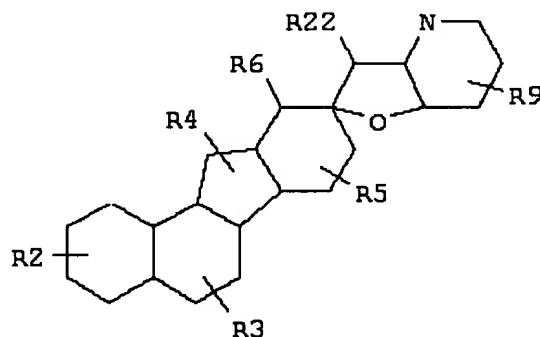
T' is absent, or represents an alkyl, an aminoalkyl, a carboxyl, an ester, an amide, ether or amine linkage of 1-3 bond lengths, wherein if T and T' are present together, ~~than~~then T and T' taken together with the ring B form a covalently closed ring of 5-8 ring atoms;

R₉ represent one or more substitutions to the ring B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxy, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$; and

n and m are, independently, zero, 1 or 2;

with the proviso that T, T' B and R₉, taken together include at least one primary or secondary amine.

7. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (IV), or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula IV

wherein

R₂, R₃, R₄, and R₅; independently for each occurrence, represent one or more substituents selected from ~~represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent~~ hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

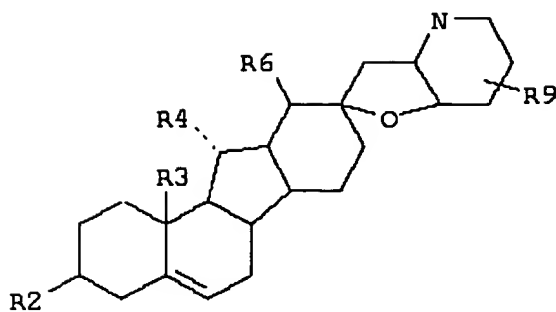
R₆ is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle;

R₉ represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or -(CH₂)_m-R₈; and

R₂₂ is absent or represents an alkyl, an alkoxyl or -OH.

8. (Amended) A method for inhibiting unwanted hair growth or inhibiting spermatogenesis, comprising administering to the patient a composition comprising a purified steroidal alkaloid represented in the general formula (V) or unsaturated forms thereof and/or seco-, nor- or homo-derivatives thereof:



Formula V

wherein

R₂, R₃, and R₄, independently for each occurrence, represent one or more substituents selected from ~~represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent~~ hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R₃ independently for each occurrence, represents one or more substituents selected from hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R₆ is absent or represents halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and

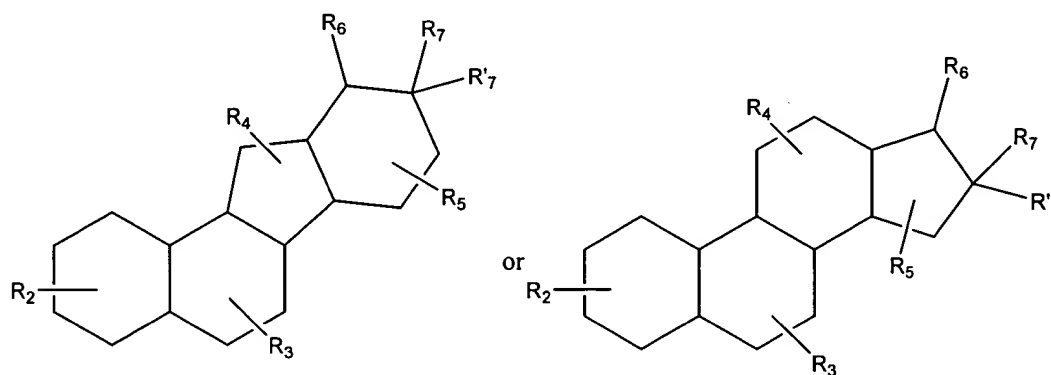
R₉ represents one or more substitutions to the ring A or B, which for each occurrence, independently represent halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates,

phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$.

11. (Amended) The method of any of claims 3-8, wherein the steroidal alkaloid does not substantially interfere with the biological activity of such steroids as aldosterone, androstane, androstene, androstenedione, androsterone, cholecalciferol, cholestane, cholic acid, corticosterone, cortisol, cortisol acetate, cortisone, cortisone acetate, deoxycorticosterone, digitoxigenin, ergocalciferol, ergosterol, estradiol-17- α , estradiol-17- β , estriol, estrane, estrone, hydrocortisone, lanosterol, lithocholic acid, mestranol, β -methasone, prednisone, pregnane, pregnenolone, progesterone, spironolactone, testosterone, triamcinolone ~~and their derivatives~~.
12. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind a nuclear hormone receptor.
13. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid does not specifically bind estrogen or testosterone receptors.
14. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid has no estrogenic activity at therapeutic concentrations.
15. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 mM or less.
16. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 μ M or less.
17. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid inhibits hedgehog-mediated signal transduction with an ED_{50} of 1 nM or less.
20. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is administered as part of a therapeutic or cosmetic application.

22. (Reiterated) The method of any of claims 3-8, wherein the steroidal alkaloid is applied as a topical formulation.

24. (Reiterated) A pharmaceutical preparation formulated for topical application comprising steroidal alkaloid is represented in the general ~~formulas~~ formula (I), or unsaturated forms thereof and/or seco-, nor- or homo- derivatives thereof:



Formula I

wherein, as valence and stability permit,

R_2 , R_3 , R_4 , and R_5 ; independently for each occurrence, represent one or more substituents

selected from ~~represent one or more substitutions to the ring to which each is attached, for each occurrence, independently represent~~ hydrogen, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$;

R_6 , R_7 , and R'_7 ; are absent or represent, independently, halogens, alkyls, alkenyls, alkynyls, aryls, hydroxyl, =O, =S, alkoxyl, silyloxy, amino, nitro, thiol, amines, imines, amides, phosphoryls, phosphonates, phosphines, carbonyls, carboxyls, carboxamides, anhydrides, silyls, ethers, thioethers, alkylsulfonyls, arylsulfonyls, selenoethers, ketones, aldehydes, esters, or $-(CH_2)_m-R_8$, or

R₆ and R₇, or R₇ and R'₇, taken together form a ring or polycyclic ring, ~~e.g., which is~~
~~substituted~~ substituted or unsubstituted, with the proviso that at least one of R₆, R₇, or
R'₇ is present and includes a primary or secondary amine;
R₈ represents an aryl, a cycloalkyl, a cycloalkenyl, a heterocycle, or a polycycle; and
m is an integer in the range 0 to 8 inclusive.

25. (Cancelled) ~~The preparation of claim 24, formulated for topical application.~~

26. (Reiterated) A process for manufacturing a medicament comprising formulating a steroid
alkaloid inhibitor of a hedgehog signal transduction pathway in a pharmaceutically
acceptable excipient to form a sterile medicament for treating unwanted hair growth or inhibiting
spermatogenesis ~~preventing growth of cells having an aberrant activation hedgehog pathway.~~

REMARKS

Claims 3, 5-8, 11-17, 20, 22 and 24-26 constitute the pending claims in the present application. Applicants have amended claims 5 and 6 by removing =O and =S from the possible functional groups for R₃ and R₅. Applicants have amended claim 8 by removing =O and =S from the possible functional groups for R₃. Applicants have amended claim 11 by removing the phrase “and their derivatives.” Applicants have amended claim 24 by adding the phrase “formulated for topical application”; by replacing the terms “formulas” and “substituted” with the terms “formulae” and “substituted” respectively; and by removing the phrase “e.g., which is.” Applicants have cancelled claim 25. Applicants have amended claim 26 by replacing the term “preventing growth of cells having an aberrant activation hedgehog pathway” with “treating unwanted hair growth or inhibiting spermatogenesis.” Applicants assert that the aforementioned amendments have been submitted solely to expedite prosecution. Applicants reserve the right to pursue the claims in their unamended forms, or claims with substantial similarity thereto, at a later date. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action. Applicants respectfully request reconsideration in view of the following remarks.